IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

IN RE: PARAGARD IUD PRODUCTS LIABILITY LITIGATION	:	MDL DOCKET NO. 2974 1:20-md-02974-LMM
This document relates to: Pauline Rickard Melody Braxton Alisa Robere	:	CIVIL ACTION NOs.: 1:21-cv-03861-LMM [48] 1:22-cv-00490-LMM [47] 1:22-cv-01583-LMM [56]

ORDER

This multi-district litigation ("MDL") involves the contraceptive Paragard, an intrauterine device ("IUD"), which is regulated as a drug under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., and the federal Food and Drug Administration's ("FDA") implementing regulations in Title 21 of the Code of Federal Regulations. The matter is before the Court on Defendant's motion to exclude certain general opinions of Labib Ghulmiyyah, M.D., from evidence in support of the claims of bellwether plaintiffs Pauline Rickard, Melody Braxton, and Alisa Robere (collectively, "Plaintiffs").[1] Upon due consideration, the Court enters the following Order.

[1] "Teva" or "Defendant" refers collectively to Defendants Teva Pharmaceuticals USA, Inc.; Teva Women's Health, LLC; and Teva Branded Pharmaceutical Products R&D, Inc. Defendant CooperSurgical, Inc. ("Cooper"), which jointly filed the present motion with Teva, was granted summary judgment of Plaintiffs' claims in other Orders. See Dkt. Nos. [116, 137, 138].

I. BACKGROUND

Paragard is an IUD that is implanted into a patient by a healthcare provider. It is a T-shaped device that is made of polyethylene milled with barium sulfate and wrapped in copper. It is indicated for intrauterine contraception for up to 10 years. The T-shape is designed to collapse for insertion and removal. It is supposed to be easy for a healthcare practitioner to remove the Paragard by gently pulling on attached threads.

Paragard has been approved and regulated by the FDA since 1984 without any significant design updates. Teva became the owner of the Paragard NDA in December 2008. Cooper acquired the Paragard NDA from Teva on November 1, 2017.

Robere underwent placement of a Paragard in June 2011, Rickard had hers placed in May 2012, and Braxton had hers placed in November 2014. At the time Plaintiffs had their Paragards placed, there was nothing in the Warnings, Adverse Reactions, or Patient Information sections of the drug label about breakage, and each plaintiff expected for the removal of her Paragard to be simple and easy. But in each case—when Robere and Braxton had their Paragards removed in or around December 2019 and when Rickard had hers removed in August 2021—the Paragard was broken, and it was necessary for the plaintiff to have surgery to remove fragments of the Paragard.

Dr. Ghulmiyyah is a board-certified obstetrician-gynecologist and maternal-fetal medicine specialist with over two decades of experience.

Dr. Ghulmiyyah has submitted an expert report in which he opines that the Paragard carries an elevated risk of breakage and related complications compared to other IUDs; Paragard breakage carries serious and distinct clinical risks, including major surgical interventions, which have potentially life-changing consequences for patients; Paragard's propensity to break is a consequential risk that should be clearly communicated to patients and healthcare providers, who in turn should counsel patients; and the Paragard label does not adequately warn healthcare providers of the risk of breakage. Dkt. No. [48-1] at 6.[2]

Defendant seeks to exclude certain portions of Dr. Ghulmiyyah's testimony and opinions under Rule 702 of the Federal Rules of Evidence. It argues that Dr. Ghulmiyyah's warnings opinions should be excluded because they are inconsistent with Florida law and thus unhelpful to the trier of fact; that his opinion that Paragard breaks more often than other IUDs does not fit the facts of the case and thus is unhelpful to the trier of fact; and that his opinion that Paragard presents an elevated risk of breakage is unreliable. Dkt. No. [48].

The Court will first review the legal standards guiding adjudication of a motion to exclude evidence under Rule 702. It will then consider Defendant's arguments in logical order.

[2] Unless otherwise noted, record citations are to the documents filed in Rickard v. Teva Pharms. USA, Inc., Civ. Case No. 1:21-cv-03861-LMM (N.D. Ga.).

II. LEGAL STANDARD

Rule 702 of the Federal Rules of Evidence governs the admissibility of proposed expert evidence:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if the proponent demonstrates to the court that it is more likely than not that:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert's opinion reflects a reliable application of the principles and methods to the facts of the case.

The trial court, as the evidentiary gatekeeper, must determine that the testimony is "sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute." Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 591 (1993) (cleaned up). The trial court must also "make certain that an expert . . . employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Kumho Tire Co. v. Carmichael, 526 U.S. 137, 152 (1999).

The Eleventh Circuit has synthesized the existing rules into a three-part inquiry, instructing courts to consider whether: (1) the expert is qualified to testify competently regarding the matters he intends to address; (2) the

methodology by which the expert reaches his conclusions is sufficiently reliable as determined by the sort of inquiry mandated in Daubert; and (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue. City of Tuscaloosa v. Harcros Chems., Inc., 158 F.3d 548, 562 (11th Cir. 1998).

With regard to the second factor, the Supreme Court explained in Daubert and its progeny that courts should serve a gatekeeping function in order to ensure the reliability of the methods employed by expert witnesses. 509 U.S. at 589. The Daubert inquiry specifically addresses the reliability of an expert's principles and methods. Daubert lists factors for courts to consider, including: whether the theory or technique in question can be (and has been) tested; whether the theory or technique has been subjected to peer review and publication; the known or potential rate of error; and general acceptance of the theory in the field. Daubert, 509 U.S. at 593-94. Additional factors courts have used to assess reliability of expert methods include whether the opinion naturally flowed from an expert's research or was developed specifically for litigation, and whether an expert has improperly extrapolated from a scientifically founded proposition to an unfounded conclusion. Daubert v. Merrell Dow Pharms., Inc., 43 F.3d 1311, 1317 (9th Cir. 1995); Allison v. McGhan Med. Corp., 184 F.3d 1300, 1312, 1314, 1321 (11th Cir. 1999).

But "expert testimony that does not meet all or most of the Daubert factors may sometimes be admissible." United States v. Brown, 415 F.3d 1257, 1268 (11th Cir. 2005). Indeed, reliability is meant to be a flexible inquiry for district courts, allowing them to determine which factors may be relevant and to apply only those factors which the court sees fit. United States v. Frazier, 387 F.3d 1244, 1262 (11th Cir. 2004). "The burden of laying the proper foundation for the admission of the expert testimony is on the party offering the expert, and admissibility must be shown by a preponderance of the evidence." Allison, 184 F.3d at 1306. However, "the proponent of the testimony does not have the burden of proving that it is scientifically correct, but that by a preponderance of the evidence, it is reliable." Id. at 1312.

The trial court has a great deal of flexibility in the inquiry into the reliability of an expert. Daubert, 509 U.S. at 595. This flexibility includes "latitude in deciding how to test an expert's reliability, and to decide whether or when special briefing or other proceedings are needed to investigate reliability." Kumho Tire, 526 U.S. at 152.

"In the end, although rulings on admissibility under Daubert inherently require the court to conduct an exacting analysis of the proffered expert's methodology, it is not the role of the district court to make ultimate conclusions as to the persuasiveness of the proffered evidence." Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK Ltd., 326 F.3d 1333, 1341 (11th Cir. 2003) (internal citations and quotation marks omitted). "Quite the contrary, '[v]igorous cross-

examination, presentation of contrary evidence and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.'" Id. (quoting Daubert, 509 U.S. at 596) (alteration in Quiet Tech.).

III. DISCUSSION

Dr. Ghulmiyyah is a double board-certified OB/GYN and maternal-fetal medicine specialist. He graduated from medical school at the American University of Beirut in 2000, completed an internship at Case Western University, and finished his OB/GYN residency at Atlanta Medical Center from 2001 to 2005. He then completed a three-year maternal-fetal medicine fellowship at the University of Texas at Galveston. After his fellowship, he practiced in Lebanon from 2008 until 2020, when he returned to the United States. Since 2020, he has practiced at the University of Miami for two years and then at Broward General Hospital for three years, focusing primarily on maternal-fetal medicine while maintaining some OB/GYN practice.

Dr. Ghulmiyyah has extensive experience with IUDs. During his residency, he was trained primarily on Paragard, inserting more than 100 of them. To date, he has inserted approximately 1,600 IUDs and removed about 400 IUDs. During his practice in Lebanon, he placed both copper and hormonal IUDs, with approximately 30 to 40% being copper-based and the remainder being hormonal. Of the 400 IUDs he has removed, approximately 30 to 40% were copper IUDs (including Paragard and non-Paragard copper IUDs used in Lebanon), with the

remainder being hormonal IUDs. He estimates he has removed at least 50 to 60 Paragard IUDs specifically. In his current practice, he places about two to three IUDs per month, with his most recent Paragard placement occurring approximately four weeks before his deposition.

A. Sufficiency of the label as a matter of law

Defendant argues that Dr. Ghulmiyyah's opinions on the sufficiency of the warnings on the Paragard label will not be helpful to the finder of fact because the warnings were already adequate under Florida law.[3] See Dkt. No. [48] at 11-15. The Court held on summary judgment, without reliance on Dr. Ghulmiyyah's expert report, that there is a genuine issue of material fact as to whether the label adequately warned of the risk of breakage. Dkt. No. [149] at 7-11. Thus, the adequacy of the label's warnings and the reasons the label's warnings may not have been adequate are still open questions. Dr. Ghulmiyyah's testimony therefore will not be limited on this basis.

B. Dr. Ghulmiyyah's testimony on the sufficiency of the label

Defendant also argues that Dr. Ghulmiyyah's labeling opinions are without foundation because he made clear at his deposition that he does not believe that Paragard's label became deficient until some point around 2020—years after Plaintiffs had their Paragards placed. Dkt. No. [48] at 17-18. The Court has

[3] The parties have determined that Florida law applies to the substantive claims of each of the bellwether plaintiffs.

reviewed the cited deposition testimony and finds that this argument relies on a misinterpretation of the testimony.

The transcript requires somewhat close reading. It is nevertheless clear that Dr. Ghulmiyyah consistently testified that he believed that the Paragard label was inadequate at the time Plaintiffs had their Paragards placed because it did not discuss the risk of breakage in the Warnings, Precautions, or Adverse Reactions sections. See, e.g., See Sept. 6, 2025, Deposition of Labib M. Ghulmiyyah, M.D. ("Gen. Ghulmiyyah Dep.") at 281-83, 298-99, 301, 319-20, 322-23. It is also clear in the testimony Defendant cites that when Dr. Ghulmiyyah was talking about his perception in 2020 that the Paragard contained insufficient warnings, he was explaining not that Defendant only began to receive breakage reports in 2020 but instead that it had become plain to him by that point as a physician that the breakage warnings were insufficient because he had begun seeing news stories about IUD breakage. See id. at 299-305; Sept. 8, 2025, Deposition of Labib M. Ghulmiyyah, M.D. ("CS Ghulmiyyah Dep.") at 33-34.

Accordingly, the Court finds no basis in this argument for excluding Dr. Ghulmiyyah's opinion that the warnings on the Paragard label did not adequately convey the risk of breakage.

C. Reliability of Dr. Ghulmiyyah's opinions on relative breakage rates

Dr. Ghulmiyyah opines that Paragard breaks more frequently than other IUDs. Dkt. No. [48-1] at 15. In support of the statement, he cites two studies, Fernandez (2021) and Latack (2022). Id.

Defendant argues that the Court should preclude Dr. Ghulmiyyah from testifying that Paragard's propensity to break is greater than that of other IUDs because he concedes that the Paragard breakage rate has not been calculated, and neither of the studies Dr. Ghulmiyyah relies upon indicate that Paragard's propensity to break is greater than other IUDs. Dkt. No. [48] at 20-24. The Court agrees that Dr. Ghulmiyyah has not supplied a reliable foundation for the comparison.

Plaintiffs argue that "Dr. Ghulmiyyah's opinion is plainly supported" by the Fernandez and Latack studies. However, Dr. Ghulmiyyah conceded in his deposition that the Fernandez sample (13 broken IUDs) was too small to determine an incidence rate for Paragard breakage, Gen. Ghulmiyyah Dep. at 233-40, 248-50, and that the Latack study did not even attempt to calculate an incidence rate for Paragard breakage, id. at 251. Instead, what Latack showed was device breakage as a percentage of adverse event reports for Paragard and device breakage as a percentage of adverse event reports for all hormonal IUDs—not device breakage as a percentage of the number of each type of IUD in use. Dkt. No. [48-9] at 2-4.

Thus, neither Fernandez nor Latack provides a foundation for comparing the rate of Paragard breakage to the breakage rate of other IUDs. Because Dr. Ghulmiyyah does not supply any other foundation for the opinion that Paragard breaks more frequently than other IUDs, that opinion must be excluded.

The Latack study does reveal other relevant information, such as the increase in the raw number of Paragard breakage reports nearly every year since 1998. See id. at 4. However, Dr. Ghulmiyyah is limited from testifying as to breakage *rates*.

D. Warnings about the specific frequency of breakage

Dr. Ghulmiyyah faults the label for "fail[ing] to adequately notify healthcare professionals and patients about the injuries and complex sequalae that may result from breakage, as well as the frequency of breakages." Dkt. No. [48-1] at 29. Defendant argues that Dr. Ghulmiyyah should be precluded from testifying that the label should have warned of "the frequency of breakages" because neither Florida law nor FDA regulations require such detailed information and because Dr. Ghulmiyyah himself concedes that the incidence rate for breakage is unknown and cannot be calculated. Dkt. No. [48] at 15-16.

This argument is also well taken. Dr. Ghulmiyyah concedes that the Paragard breakage rate is unknown and either has not been or cannot be calculated. Gen. Ghulmiyyah Dep. at 140, 177, 285-87. As discussed immediately above, the studies he cites also do not establish a breakage rate. See supra

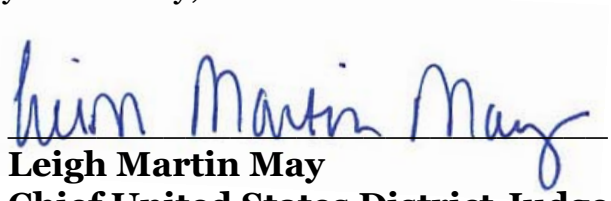
Part III.C. Thus, Dr. Ghulmiyyah has not established a factual basis for his opinion that Defendant should disclose the frequency of breakage on the label.

This is not to say that Dr. Ghulmiyyah cannot testify that the general increase in the raw number of incident breakage reports could have and should have signaled to Defendant that it was necessary to add breakage warnings to the Paragard label. The Court does not have a problem with Dr. Ghulmiyyah's concept of adverse event reports influencing whether there should have been an earlier change to the warnings on the Paragard label. However, he will be limited from testifying that Defendant should have disclosed the "frequency" of breakages on the label.

IV. CONCLUSION

Defendant's motion to exclude certain general opinions of Labib Ghulmiyyah, M.D., from evidence in the bellwether cases is **GRANTED IN PART and DENIED IN PART**, as set out above.

IT IS SO ORDERED this 9th day of January, 2026.



Leigh Martin May
Chief United States District Judge